UAB IRB
SAMPLE CONSENT FORM
ENGLISH
VERSION DATE: 02.01.17

Note: It is not possible to address all scenarios for all types of studies conducted by UAB researchers. This sample is designed to assist you in creating your consent form. It is intended to show language preferred by the UAB IRB to address the required elements of informed consent. In many cases, the sample language will need to be modified, deleted, or expanded for the particular study.

Shaded paragraphs like this one are instructions for you, the writer. Do not include them in the consent form you submit. If the instructions indicate that specific language applies to your protocol, the specific language will be shown below the instructions outside of the shaded paragraph.

Use this sample consent form as a guide for obtaining consent and/or assent from participants 14 years of age and older.

Formatting Instructions

- Use a 12 pt font for the consent form.
- Write the consent form in the 2nd person (i.e., you) and keep the pronoun usage consistent throughout.
- Use *Page X of Y* numbering on each page.
- Leave an area approximately 1 inch at the bottom right of the first page for the IRB approval stamp.

Use understandable, non-technical language at an 8th-grade or lower reading level.

- Readability statistics can be displayed in Microsoft Word. Search Microsoft Office Help for "readability statistics" for further instructions.

DELETE THIS FIRST PAGE OF INFORMATION
IF YOU ARE USING THIS DOCUMENT
TO CREATE YOUR CONSENT FORM.

CONSENT FORM

Title of Research: Evaluation of the Safety and Efficacy of Trimycin vs. Hydrochlorothiazide in the Treatment of Hypertension

UAB IRB Protocol #: #########

Principal Investigator: John Doe, M.D.

Sponsor: If the protocol is being sponsored by UAB departmental funds or is unfunded, put the name of the department here (e.g., UAB Department of Medicine). For student research, include the student's departmental affiliation.

If additional or other support is being provided, include this information with a heading such as "**SUPPORTED BY**:" after the SPONSOR line.

Sponsor: Wise Drug Company, Inc.

If no **Sponsor Protocol #**, remove the heading

Sponsor Protocol #: WDC223

RESEARCH INVOLVING CHILDREN - WHEN TO INSERT "FOR CHILDREN…" BOX:

- When a parent or guardian is providing consent only for a child participant & that child participant will sign *the assent section of the consent* form, do not use "you/your child" throughout the form. Instead, use "you" and insert the following text before the Purpose of the Research section:

For Children (persons under 18 years of age) participating in this study, the term "You" addresses both the participant ("you") and the parent or legally authorized representative ("your child").

RESEARCH INVOLVING CHILDREN - WHEN NOT TO INSERT "FOR CHILDREN…" BOX:

- When a parent or guardian is providing consent only for a child participant & that child participant will sign *a separate assent form or will not provide written assent*, use "your child" throughout the form.
- When a parent or guardian is providing consent for both him/herself and a child participant, specify throughout the consent form when you are referring to the parent and when you are referring to the child. This would allow for the use of "you," "your child," and "you and your child" throughout the form when appropriate.

Purpose of the Research

- Explain the purpose of the study in nontechnical language.
- Describe why the participant is being asked to join.
- State that the study involves research.
- If drugs or devices are used, indicate whether they are FDA approved or investigational.
- If applicable, define "Pilot", "Phase I", "Phase II, "Phase III", or "Phase IV" drug study.
- State the total planned number of participants (e.g., individuals, records, specimens) to be enrolled by the UAB investigator, and studywide for multicenter studies.

We are asking you to take part in a research study. The purpose of this research study is to test how well a new drug lowers blood pressure. The new drug, Trimycin, is investigational and not yet approved by the Food and Drug Administration (FDA). People who enter the study will take either the new drug, Trimycin, or Hydrochlorothiazide (water pill). Hydrochlorothiazide is the FDA approved drug for people to take to lower their blood pressure. More than 200 people in other research studies in the United States have safely used Trimycin. This is a Phase III study. A Phase III study is a research study that tests the effectiveness and monitors side effects of a drug, and compares it to commonly used treatments. This study will enroll 200 participants nationwide. There will be 20 participants enrolled at UAB.

Explanation of Procedures

- Describe the procedures to be followed, identifying which procedures are for research and which procedures are standard of care.
- Use bulleted lists where necessary to make easier to read.
- Identify if any procedures are experimental.
- Estimate the amount of time involved in study participation.
- If specimens (e.g., blood, tissue, body fluids) will be collected as part of this research, describe the collection in this section. If the specimens will be stored for future research, describe the storage procedures under the "Storage of Specimens for Future Use" section.

If you agree to join the study, all of your current blood pressure medicines will be stopped for 1 month. During this time, you will be given pills called placebos. A placebo does not have any active medicine, so it should not have any effect on your blood pressure. However, this placebo might lower your blood pressure. The study staff will watch your blood pressure closely while you are not on any medicine for your blood pressure. Your blood pressure will be watched to make sure it does not rise so high that you need immediate treatment.

- You will come for office visits three times during the first week off your medication.
- You will come for office visits two times per week during Weeks 2, 3, and 4.
- If your blood pressure is in the range required by the study after Week 4, you will be entered into the study. If your blood pressure is not in the range required by the study after Week 4, you will not be entered into the study and will receive standard care for your blood pressure.
- If you are entered and complete the entire study, you will be in the study for 6 months.

- If randomization is part of the study, explain what randomization is and how it is done.
- If the study is blinded, explain what blinded means.
- If the study involves a placebo,
    - define placebo (not as *treatment* or *medication*; see paragraph above that begins "*If you enter the study…"*)

You will be randomly picked (like the flip of a coin) by a computer to receive either Trimycin or Hydrochlorothiazide. You will take the study drug you receive once a day by mouth. This is a double-blind study. This means neither you nor your doctors will know which study drug you are taking. If necessary, the doctor can find out which you are taking.

These tests will be made during the study:

- lab blood tests
- urine tests
- weight measures
- resting electrocardiogram (measures the electrical activity of the heart)
- heart rate
- blood pressure

You will be asked to come back to the clinic for 20 weekly visits after you begin the study drug. At each visit you will be asked how you are feeling on the study drug and about any side effects.

If drug screening is part of the protocol, include a statement such as:

If you have used any illicit (street) drug(s) within the past 3 months, we ask that you not participate in this project.

Where HIV testing is conducted, individuals whose test results are associated with personal identifiers must be informed of their own test results and provided the opportunity to receive appropriate counseling before and after the testing.

Where other protocol testing for reportable diseases is conducted, individuals will be informed of the results and told where to obtain counseling and referred to their primary care physician or the state health department.

If research-only imaging studies are part of the protocol, address whether or not the images will be read for incidental findings. If the images will <u>not</u> be read for incidental findings, include the following:

We are performing imaging solely for the research purposes described above. It is not a clinical scan intended for diagnostic or therapeutic purposes. Under no circumstance will the investigator, research staff, or imaging staff interpret the scan as normal or abnormal. They are unable to make any medical comments about your scan. The scan will not be looked at or read for any healthcare treatment or diagnostic purpose. If you want your scan to be reviewed by a physician so the physician can look for medical issues, you can request a copy of your scan. We will provide an electronic copy at no charge.

<u>Risks and Discomforts</u>

- Include any foreseeable risks or discomforts to the participant (e.g., physical, social, financial, loss of employability, reputation, and breach of confidentiality).
- When possible, quantify the risks involved (e.g., "*frequent, common*, *occasional, rare;"*, *or percentages*).
- Use bulleted lists where necessary to make easier to read.
- If the study involves a placebo,
    - include the risks of the placebo group and what complications may result
    - describe the precautions that will be taken to protect the participant during this time.
- Do not include risks or discomforts associated with drugs or interventions that are not being administered or performed as part of this study.

You may have some side effects from taking the study drugs.

The side effects of Trimycin are:

- headaches
- feeling sleepy
- feeling tired

About forty percent (40%) of people who take Trimycin have reported feeling drowsy and tired. About twenty percent (20%) of people who take Trimycin have headaches.

The side effects of Hydrochlorothiazide are:

- low blood potassium
- rise in blood uric acid which can cause crystals to form in the joints
- rise in blood sugar
- lowering of red and white blood cells

About eighty percent (80%) of people who take Hydrochlorothiazide have these problems.

There may also be risks that are unknown at this time. You will be given more information if other risks are found.

Randomization: If your protocol involves randomization, include a paragraph on risks of randomization. Ensure the risks of all study arms are described in detail in this section, even if the procedures in those arms would be standard of care if the participant was not in the study. An example paragraph is below; however, you should revise as applicable to your study.

You will be assigned to a group by chance, which may prove to be less effective or to have more side effects than the other study group or alternatives.

Information for Women of Childbearing Potential, Nursing Mothers, and/or Men Capable of Fathering a Child

If applicable, include this section and address the precautions that should be taken by women of childbearing potential and/or by men capable of fathering a child before, during, and/or after participation. List the specific acceptable methods of birth control for participants involved in the study. Use only the information that is applicable to the study population.

We do not know if the study drug will affect mother's milk or an unborn fetus. Therefore, breast-feeding and pregnant women are not allowed to take part in the study. If you are pregnant or become pregnant, there may be risks to the embryo or fetus that are unknown at this time. Women who can become pregnant must take a pregnancy test before the start of the study.

You should not father a child while on this study as the treatment may indirectly affect an unborn child. If you are sexually active and are at risk of causing a pregnancy, you and your female partner(s) must use a birth control method to avoid pregnancy that works well or you must not have sex.

Unless you cannot have children because of surgery or other medical reasons, you must have been using an effective form of birth control before you start the study. You must also agree to continue to use an effective form of birth control for 6 months after taking the study drug. Effective birth control includes birth control pills, patch, IUD, condom, sponge, diaphragm with spermicide, abstinence, or any other method prescribed by your physician.

Benefits

- State any potential benefits to the participant or to others that may reasonably be expected from the research.
- Do not overstate benefits.
- If there is no potential for direct benefit to the participant, that should also be stated.
- **Do not include** medication, treatment, devices, or compensation information.

You may not benefit directly from taking part in this study. However, this study may help us better understand how to treat high blood pressure in the future.

Alternatives

- Include appropriate alternative procedures or courses of treatment that may be advantageous to the participant.
- One alternative may be to not participate in the study.

There are many other drugs that are used to treat high blood pressure. Some examples of these drugs are Betasan, Enapror, and Ditserin. The investigator or research staff will discuss these other drugs with you.

Confidentiality

- Include information regarding anyone who will receive identifiable data (e.g., through subcontracts or other agreements).
- Include the US Food and Drug Administration (FDA) if the research involves a drug, device, or biologic subject to FDA oversight.
- Include other locations (e.g., Jefferson County Department of Health), if applicable.
- Include the language regarding the medical record, if applicable.

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- the UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- [add sponsor name(s)]
- the Food and Drug Administration (FDA)
- the Office for Human Research Protections (OHRP)

The information from the research may be published for scientific purposes; however, your identity will not be given out.

Medical Record: If the consent form will be placed in the participant's medical record at UAB Health System and/or Children's of Alabama, include the following:

Your consent form will be placed in your medical record at UAB Health System or Children's of Alabama. This may include either a paper medical record or electronic medical record (EMR). An EMR is an electronic version of a paper medical record of your care within this health system. Your EMR may indicate that you are on a clinical trial and provide the name and contact information for the principal investigator.

If you are receiving care or have received care within this health system (outpatient or inpatient) and are participating in a research study, results of research tests or procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing medical record.

If you have never received care within this health system (outpatient or inpatient) and are participating in a research study, a medical record will be created for you to maintain results of research tests or procedures.

Results of research tests or procedures may be placed in your medical record. All information within your medical record can be viewed by individuals authorized to access the record.

Billing Compliance Language: If "clinical billable services" will be provided at any UAB Health System location (i.e. HSF Clinics, UAB Hospital, UAB Highlands, or Callahan Eye Foundation) or Children's of Alabama, include the following language, as applicable.

If you have questions about clinical trial billing at a UAB Health System location, contact the Office of Clinical Billing Review at fap@uab.edu. For more on FAP requirements, go to FAP - Site Minder Processes. If you have questions about clinical trial billing for studies conducted at Children's of Alabama, contact Pam Barlow at pam.barlow@childrensal.org or 558-2452.

Information relating to this study, including your name, medical record number, date of birth and social security number, may be shared with the billing offices of

[UAB ONLY] UAB and UAB Health System affiliated entities
[Children's ONLY] Children's of Alabama and its billing agents
[UAB & Children's] UAB and UAB Health System affiliated entities, along with Children's of Alabama and its billing agents

so costs for clinical services can be appropriately paid for by either the study account or by your insurance.

International Protocols: If the study is conducted outside the United States or sponsored by a company based outside the United States and foreign regulatory agencies will have access to identifiable research records, include the following language:

Monitors, auditors, the Institutional Review Board for Human Use, and regulatory authorities will be granted direct access to your original medical records for verification of trial procedures and/or data without violating confidentiality.

Reportable Diseases/Conditions: If the investigator will be testing for any reportable diseases/conditions, include the following language specifying what reportable diseases/conditions are being tested and that positive results will be reported to the county or state health department.

As part of this study, you will be tested for [specify disease/condition]. If the results show that you are positive for [specify disease/condition], the study staff will tell you the results. The study staff will be required to give your name to the Alabama Department of Public Health if you test positive because this is the law.

Screening for Drugs, Observations of Abusive Behavior: If the investigator will conduct drug screening or inquire about abusive behavior (e.g., child or elder abuse or neglect, or harm to self) as part of the protocol, include the following language:

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

ClinicalTrials.gov: If the protocol meets the definition of a clinical trial, it must be registered on Clinical Trials.gov. and you must include the following language.

If you have any questions regarding registering a study on ClinicalTrials.gov, email the UAB Center for Clinical and Translational Science at ccts@uab.edu.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Genetic Research: Only if the research involves genetic testing, describe the protections provided to the participant under GINA. For questions regarding GINA, see the IRB Guidebook. Include the following language:

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and some employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by some employers.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

- Include the consequences of a participant's decision to withdraw from the research.
- Include procedures for how the participant should withdraw. (An example paragraph is below; however, you should revise as applicable to your study.)

You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution. However, you should return to see the study doctor for safety reasons so you can be taken off the study drug and referred for follow-up care. Contact the study doctor if you want to withdraw from the study.

- If applicable, include anticipated circumstances under which the PI without regard to the participant's consent may terminate the participant's involvement. (An example paragraph is below; however, you should revise as applicable to your study.)

You may be removed from the study without your consent if the sponsor ends the study, if the study drug is approved by the FDA, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If students or employees of UAB are recruited to participate in the study, include the following language:

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

- If any costs to the participant or the participant's health insurance might result from the research (e.g., for tests, drugs, biologics, devices, or copayments), describe those costs. Include information about any financial assistance that may be available, such as how to consult a social worker.
- If there is no cost to the participant, this should be stated.

There will be no cost to you for taking part in this study. All drugs, exams, and medical care related to this study will be provided to you at no cost during the 6-month study period.

If standard medical care may be provided during the study include the following statement:

The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner.

If participants may be enrolled in Medicare Advantage and will have study related services billed to their Medicare Advantage insurance, include the following statement. If you have questions regarding the inclusion of this statement, contact the Fiscal Approval Process (FAP) staff at FAP@uab.edu.

If you are in Medicare Advantage (Medicare managed care plan), you should contact someone at your plan before you start a clinical trial. They can provide more information about additional costs you could incur from participating in clinical trials.

Category B Medical Devices: If a Category B medical device is used in the study, include the following statement:

Your insurance company may or may not pay for the device(s) used in this study. Your insurance company may decline to cover these types of devices. Therefore, it is very important that you provide your current health insurance information to UAB and that you check with your insurance company about the costs of participation.

Payment for Participation in Research

- Note: Payment may not be based upon successful completion of the protocol.
- Specify the amount of compensation a participant will receive for participating OR specify there is no compensation for participation.
- If applicable, include the payment schedule.
- Describe prorated payments for participants who withdraw before the end of the study.
- If children are involved, specify whether the child or parent is being paid.

You will be paid $10 for each study visit, including the placebo phase of the study. If you withdraw from the study, you will be paid $10 for each study visit made to the clinic. Payments will be made after 3 months and 6 months if you complete the entire study. The total payment you may receive is $290. If you do not finish the entire study, you will be paid at the time you decide to stop taking part in the study. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

If a participant is to earn $600 or more in a calendar year from their participation in research, include the following language:

You are responsible for paying any state, federal, Social Security or other taxes on the payments you receive. You will receive a form 1099 in January of the year following your participation in this study. This form is also sent to the IRS to report any money paid to you. No taxes are kept from your payment.

Payment for Research-Related Injuries

- Include this section only if the research involves (a) greater than minimal risk or (b) procedures or interventions that could result in harm or injury.
- If the section is to be included, include the UAB statement below.

- Include other locations (e.g., Jefferson County Department of Health), if applicable.

UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

In addition, if the research is sponsored, include language that addresses whether or not the sponsor(s) will provide compensation for research-related injuries.

- For sponsored research where the sponsor(s) **will not** pay for compensation to injured research participants or pay for medical treatment of research-related injuries, list the names of all sponsors after "UAB".

UAB and Wise Drug Company, Inc. have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

- For sponsored research where the sponsor(s) **will** pay participants for either compensation or treatment for research-related injuries, include the specific language provided by the sponsor(s) regarding injury compensation. The IRB must be provided with "sponsor verification" in the form of a letter signed by the sponsor(s) with the same wording given in the consent form, a model consent form included in the protocol and listed in the Table of Contents of the protocol with the same wording, or in the contract or agreement. Do not submit a copy of the indemnification letter as the verification. Include information regarding what medical treatment will consist of if injury occurs and where further information may be obtained.

Significant New Findings

Indicate that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided to the participant by the principal investigator or his/her staff.

You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Optional Research

Please note: This section of the consent form is about optional research that is being done with people who are taking part in this study. You may take part in this optional research if you want to. You can still be a part of this study even if you say no to taking part in any of the optional research.

You can say "yes" or "no" to each of the following studies. Please mark your choice for each study.

[Insert information about optional studies here. Provide initial lines to agree/disagree at each decision point.]

Storage of Specimens for Future Use *[this subsection should be indented under the Optional Research section header and introduction information]*

If the study includes the storage and use of specimens for future research (research not specifically defined in the protocol), address the following points and include lines for participants to initial (do not use checkboxes):

- What kind of specimens will be collected and how they are collected
- What type of research will be done with the specimens
- Whether the specimens will be shared with other investigators and if so, whether they will be shared outside UAB
- Whether the specimens will be coded or anonymized (no way of tracing back to participant/uncoded or code destroyed)
- Whether the participant may be contacted for additional consent
- How long will the specimens be stored
- Foreseeable risks or benefits to participants in the collection, storage, and subsequent research use of specimens
- Potential for commercial use of the subject's specimen(s)
- How to withdraw consent for future use

**If the study is a repository/database study -or- if participation in a repository/database component is required for participation, include this information in the Explanation of Procedures section and do not create a separate Storage of Specimens for Future Use section. Initial lines would not be necessary if that is the case.

The following is an example of the language that may be used:

As part of this study, we would like to store some of the [*specify type*] specimens collected from you for future research [*specify disease or disorder*]. The future research may be conducted by the study doctor or by other researchers that obtain IRB approval for their research. The specimens will be labeled with a code that only the study doctor can link back to you. Results of any future research will not be given to you or your doctor. The specimens obtained from you in this research may help in the development of a future commercial product. There are no plans to provide financial compensation to you should this occur. You do not have to agree to allow your specimens to be stored in order to be part of this study.

You may request at any time that your specimens be removed from storage and not be used for future research. If you decide you want your specimens removed, you may contact the study doctor. Once the request is received, and if your specimens have not already been used for other research, they will be destroyed. If you do not make such a request, your specimens will be stored indefinitely or until used.

Initial your choice below:

___ I agree to allow my specimens to be kept and used for future research on [*specify disease or disorder*].

___ I do not agree to allow my specimens to be kept and used for future research.

Genomic Data Sharing (GDS) *[this subsection should be indented under the Optional Research section header and introduction information]*

For protocols that must meet the NIH Genomic Data Sharing (GDS) Policy, see the IRB Guidebook for more information on GDS. NIH expects investigators to obtain participants' consent for their genomic and phenotypic data to be used for future research purposes and to be shared broadly. The consent form should include an explanation about whether participants' individual-level data will be shared through unrestricted- or controlled-access repositories.

The following paragraph is an example of the language that may be used:

Genetic and other relevant study data, such as health information, may be shared broadly in a coded form for future research or analysis. We may give this data about you to other researchers or companies not at UAB, including to a [*specify public or controlled access*] government health research database. We will not give them your name, address, phone number, or any other identifiable information. Research results from these studies will not be returned to you [*if applicable, describe any rare instances where research results would be returned*].

If the data will be shared with **unrestricted**-access databases, include the following paragraph:

Public (Unrestricted-Access) Databases: Your information may be put in unrestricted-access databases. This means the information is publically available and anyone can use the database. The public database could include information of hundreds of thousands of genetic variations in your DNA code, as well as your ethnic group and sex. The only health information included will be whether you had [*specify disease*] or not. This public information will not be labeled with your name or other information that could be used to easily identify you.

If the data will be shared with **controlled**-access databases, include the following paragraph:

Controlled-Access Databases: Your information may be put in controlled-access databases. This means only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your information stored in these databases will not include any identifying information. We will replace identifying information with a code number. We will keep a master list that links your code number to your identifying information here at the UAB. Only certain study personnel for this study at UAB will have access to this master list. Researchers approved to access information in the controlled-access database will agree not to attempt to identify you.

Include the following paragraphs for all GDS:

Risks: The risk of sharing your genomic data is that someone could link the information stored in the databases back to you. If your information suggested something serious about your health, it could be misused. For example, it could be used to make it harder for you to get or keep a job or insurance or be used to discriminate against you or your family. There may also be other unknown risks.

Benefits: There is no direct benefit to you from sharing your genomic data. Allowing researchers to use your data may lead to a better understanding of how genes affect health. This may help other people in the future.

If applicable, include the following:

- An explanation that a participant can withdraw his/her data from the repository. If this option is available, include a statement that the data already distributed for approved research use cannot be retrieved.

Initial your choice below:

___ I agree for my genetic and other relevant study data, such as health information, to be shared broadly in a coded form for future research or analysis.

___ I do not agree for my genetic and other relevant study data, such as health information, to be shared broadly in a coded form for future research or analysis..

Questions

- Include the name of the Principal Investigator and his/her contact number for participants to contact regarding the research and research-related injuries.
- Include afterhours contact information.
- Include the names of additional contact personnel, if applicable.

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact the study doctor. You may contact Dr. [*specify PI*] at [*specify phone number with area code*] or after hours by paging him at [*specify number*].

Include the Office of the IRB contact information.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

- Should be in second person (i.e., you).
- The signature only indicates agreement to participate; do not include other attestations (e.g., I have had all my questions answered, etc.).

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

It is not possible to address all scenarios for signature requirements that may be needed for various types of research. These instructions and samples are designed to assist you in the preparation of the Signatures section. In many cases, the Signatures section will need to be customized for the particular study population.

- The requirements for signature lines depend upon the consent process described in the Human Subjects Protocol.
- Each signature-date line included in the Signatures section, as applicable to the research, must be signed and dated.

- All signatures must appear on the same page, but that page does not need to be a separate page with no other information.
- Each person who signs the consent form must include the date of his/her signature.
- If the research involves children (i.e., individuals younger than 18 years of age for research conducted in the state of Alabama), see "Children" under General Information in the IRB Guidebook and see Example Signatures for Research Involving Children, below.
- If the research involves pregnant women, see "Pregnant Women, Fetuses, Neonates" under General Information in the IRB Guidebook.
- A signature-date line for the participant must be included. The acceptable options are shown and described below.

Option 1

_____

Signature of Participant Date

Option 2

Legally Authorized Representatives (LAR)

- If the research proposes to obtain consent from the participant **or** the LAR, add "(or Legally Authorized Representative)" after "Signature of Participant."
- If the research proposes to obtain consent from the participant **and** the LAR, include a separate signature-date line for each person.

_____

Signature of Participant or Legally Authorized Representative Date

Option 3

_____

Signature of Participant Date

_____

Signature of Legally Authorized Representative Date

Option 4

_____

Signature of Participant 14 Years of Age and Older Date

_____

Signature of Parent or Guardian Date

- The UAB IRB usually recommends the following:
    - Waiver of assent needs to be documented for participants under 7 years of age, but these participants should be included in the consent process if possible.
    - A separate assent form should be prepared for use with, and to document the assent of, participants who are 7-13 years old.
    - Participants 14-17 years old will document their assent by signing the main consent form.

- If the IRB determines the permission of only one parent or guardian is necessary, only include one line for "Signature of Parent or Guardian".

Other Signature Lines:

Person Obtaining Consent
- All persons who obtain informed consent must be listed in the HSP.
- If the Principal Investigator always obtains consent, this line would always be signed by the Principal Investigator.

_____

Signature of Person Obtaining Consent Date

Witness (ONLY IF APPLICABLE)
Include this line **ONLY** if you will enroll illiterate participants and must have a witness, if you will use a Short Form and must have a witness, -or- have justification for adding this line written in your Human Subjects Protocol.

_____

Signature of Witness Date

Reviewed by (ONLY IF APPLICABLE)
Include this line **only if** the HSP specifies that the principal investigator will not obtain informed consent but will only review signed consent documents.

Reviewed by:

_____

Signature of Principal Investigator Reviewing Consent Document Date

Waiver of Assent
Include this section if assent of participants may be waived.

Waiver of Assent

The assent of _____ (name of child/minor) was waived because of:
Age _____ Maturity _____ Psychological state of the child _____

HIPAA Authorization (IF HIPAA APPLIES)
Include the next page as the last page of your consent form and include the pagination/version date. Complete the Research Protocol, Principal Investigator, and Sponsor Lines. No revisions may be made to the HIPAA Authorization.

University of Alabama at Birmingham

AUTHORIZATION FOR USE/DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____ **UAB IRB Protocol Number:** _____

Research Protocol: _____ **Principal Investigator:** _____

Sponsor: _____

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____

or participant's legally authorized representative: _____ Date: _____

Printed Name of participant's representative: _____

Relationship to the participant: _____